

## DETAILED ACTION

**The restriction requirement mailed 11/14/08 has been vacated due to inadvertent error setting the expiration date. The following action is the replacement.**

**Claim Status: Claims 1-388 are pending.**

### ***Response To Applicant's Restriction***

Applicant's election without traverse of Group I (claims 1-134 & 376-388) in the reply filed 8/1/08 is acknowledged. However, upon careful reconsideration, the restriction requirement mailed 7/10/08 is withdrawn. The following restriction will be required instead.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to a composition comprising a naturally occurring polyol, synthetic polyol, and isocyanate, classified in class 424, subclass 78.27.
- II. Claims 24-45, drawn to a composition comprising a naturally occurring polyol and isocyanate, classified in class 424, subclass 78.27.
- III. Claims 46-63 and 386, drawn to a composition comprising a synthetic polyol and isocyanate, classified in class 424, subclass 78.27.
- IV. Claims 64-84, drawn to a composition comprising a naturally occurring polyol and isocyanate prepolymer, classified in class 424, subclass 78.27.
- V. Claims 85-105 and 387-388, drawn to a composition comprising a crosslinker or chain-extender and isocyanate prepolymer, classified in class 424, subclass 78.27.

VI. Claims 106-134, drawn to a composition comprising a polyester urethane and filler material, classified in class 424, subclass 78.27.

VII. Claims 135-174, drawn to a method of making a composition comprising a naturally occurring polyol, synthetic polyol, and isocyanate, classified in class 424, subclass 78.27.

VIII. Claims 175-213, drawn to a method of making a composition comprising a naturally occurring polyol and isocyanate, classified in class 424, subclass 78.27.

IX. Claims 214-247, drawn to a method of making a composition comprising a synthetic polyol and isocyanate, classified in class 424, subclass 78.27.

X. Claims 248-285, drawn to a method of making a composition comprising an isocyanate prepolymer and naturally occurring polyol, classified in class 424, subclass 78.27.

XI. Claims 286-325, drawn to a method of making a composition comprising an isocyanate prepolymer and crosslinker or chain-extender, classified in class 424, subclass 78.27.

XII. Claims 326-330, drawn to a method of performing a medical procedure by applying a composition, wherein the composition is comprised of a naturally occurring polyol, synthetic polyol, and isocyanate, classified in class 424, subclass 78.27.

XIII. Claims 331-335, drawn to a method of performing a medical procedure by applying a composition, wherein the composition is comprised of a naturally occurring polyol, and isocyanate, classified in class 424, subclass 78.27.

XIV. Claims 336-340, drawn to a method of performing a medical procedure by applying a composition, wherein the composition is comprised of a synthetic polyol and isocyanate, classified in class 424, subclass 78.27.

XV. Claims 341-345, drawn to a method of performing a medical procedure by applying a composition, wherein the composition is comprised of an isocyanate prepolymer and naturally occurring polyol, classified in class 424, subclass 78.27.

XVI. Claims 346-350, drawn to a method of performing a medical procedure by applying a composition, wherein the composition is comprised of an isocyanate prepolymer and a crosslinker or chain-extender, classified in class 424, subclass 78.27.

XVII. Claims 351-355, drawn to a method of performing a medical procedure by dispensing a liquid composition into a mold, wherein the composition is comprised of a naturally occurring polyol, synthetic polyol, and isocyanate, classified in class 424, subclass 78.27.

XVIII. Claims 356-360, drawn to a method of performing a medical procedure by dispensing a liquid composition into a mold, wherein the composition is comprised of a naturally occurring polyol and isocyanate, classified in class 424, subclass 78.27.

XIX. Claims 361-365, drawn to a method of performing a medical procedure by dispensing a liquid composition into a mold, wherein the composition is comprised of a synthetic polyol and isocyanate, classified in class 424, subclass 78.27.

XX. Claims 366-370, drawn to a method of performing a medical procedure by dispensing a liquid composition into a mold, wherein the composition is comprised of an

isocyanate prepolymer and naturally occurring polyol, classified in class 424, subclass 78.27.

XXI. Claims 371-375, drawn to a method of performing a medical procedure by dispensing a liquid composition into a mold, wherein the composition is comprised of an isocyanate prepolymer and crosslinker or chain extender, classified in class 424, subclass 78.27.

XXII. Claims 376-385, drawn to a kit for promoting bone growth, classified in class 424, subclass 78.27.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI, XXII are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed comprise different components and are designed differently. For instance, Invention I is a composition comprised of a naturally occurring polyol, synthetic polyol and isocyanate, whereas Invention II comprises just a naturally occurring polyol and isocyanate. Secondly, Inventions IV and V are different from the other compositions because they comprise prepolymers and chain-extenders/crosslinkers, which are distinct components and result in materially different designs. Thirdly, Invention XXII is distinct from Inventions I-VI because Invention XXII is drawn to a kit that does not comprise the components of the composition but rather a

first and second compound. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VII-XI are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed comprise different components and are designed differently. For instance, Invention VII is process claims directed to a composition comprising a naturally occurring polyol, synthetic polyol and isocyanate, whereas Invention VIII comprises just a naturally occurring polyol and isocyanate. Secondly, Inventions X and XI are different from the other processes because they comprise prepolymers and chain-extenders/crosslinkers, which are distinct components and result in materially different designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XII-XXI are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case,

the inventions as claimed comprise different components and are designed differently. For instance, Invention XII is process claims directed to a composition comprising a naturally occurring polyol, synthetic polyol and isocyanate, whereas Invention XIII comprises just a naturally occurring polyol and isocyanate. Secondly, Inventions XV and XVI are different from the other processes because they comprise prepolymers and chain-extenders/crosslinkers, which are distinct components and result in materially different designs. Regarding the inventions that have the same components, for instance Inventions XII and XVII, the methods are distinct because one method uses a mold and the other does not. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants .

Inventions I-VI, XXII and Inventions VII-XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the composition could be made by a different process. Instead of making polyurethane from isocyanate like the instant claims, polyurethane could just be purchased. Water could then be added to the purchased product to make the composition.

Inventions I-VI, XXII and Inventions XII-XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, one could also stimulate bone growth by injecting osteoblasts into the bone.

Inventions VII-XI and Inventions XII-XXI are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Inventions VII-XI are a process of making a composition and Inventions XII-XXI are a process of using the composition. Thus, the two groups of inventions have different outcomes and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Species Election***

This application contains claims directed to the following patentably distinct species. **If applicant elects any one of Inventions I-XI**, applicant is further required to elect a specific isocyanate, as disclosed in claims 6, 29, 51, etc. In addition, applicant is required to elect the presence or absence of a radiotransparent substance and a radiopaque substance, as disclosed in claim 16, 38, 58, etc.

These species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. The isocyanate species are distinct because they are structurally different. In addition, radiotransparent or radiopaque substances can be used for diagnostics purposes and are different from compositions that do not require these compounds or substances. These species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 24, 46, 64, 85, 106, 135, 143, 175, 183, 214, 221, 248, 257, 286, and 297 generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/  
Primary Examiner, Art Unit 1611  
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